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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/947,668	10/09/1997	TRACEY C. SLEMKER	534128-002-C	6180

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STANDLEY LAW GROUP LLP  
495 METRO PLACE SOUTH  
SUITE 210  
DUBLIN, OH 43017

EXAMINER
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WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/24/2003

*25*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/947,668

Applicant(s)

SLEMKER, TRACEY C.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 43-83 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 64-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 81 and 82 is/are allowed.
- 6) ☐ Claim(s) 44-63, 79, 80 and 83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on September 2, 2003, is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The Declaration under 37 CFR 1.132 filed September 2, 2003, is insufficient to overcome the rejection of the claims based upon the prior art references as set forth in the last Office action for reasons presented below.

Claims 44-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the aforementioned Declaration, “[a]n acceptable liner for use with BK prostheses employing suction retention” was not developed until the late 1990’s (paragraphs 10-13 of said Declaration). The present application, however, only tersely discusses the liner or sleeve to be used (parent US 5,702,489: column 5, lines 53-67) and has an effective filing date of August 18, 1995 (MPEP 2164.05(a)). Moreover, the Declaration indicates that the liner introduced in the mid-1990’s was problematic because it required internal and external lubrication (paragraphs 10 and 11), yet the Applicant prefers “that the patient at least apply some sort of lubrication to the residual limb [to] facilitate in donning and removal of the prosthesis” (US 5,702,489: column 5, lines 61-64), at least in cases where the sleeve or liner is not used. Therefore, in view of the state of the prior art as characterized in said Declaration and other factors (MPEP 2164.01(a)), the original disclosure fails to enable the supposedly acceptable liner for the instant invention so that any person skilled in the art could, at the time of the present invention, make and use the invention without undue experimentation.

Claims 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. In claim 44, line 11, “the *liner*-covered residual limb” (emphasis added) lacks a proper antecedent basis.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 44-49 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter involving a human being (MPEP 2105, last paragraph). It is recommended that on line 5, “facing” be replaced by --positioned to face-- or the like in order to avoid positive recitation of the residual limb itself.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44, 45, 47, 49-53, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandmark, SE 8801686 A, in view of Fishman et al., US 5,007,937, or Lenze et al., US 5,376,131. Sandmark discloses a base 7 having a proximate surface facing a distal end of the residual limb 3 (Figure 4), a duct 6, 11 extending through the socket 8 and connected to the channel defining the interior of the base 7. A valve coupled to the duct 6, 11 would have

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been obvious, if not inherent, in order to provide a readily accessible means for shutting off the vacuum and/or pressure without having to reach the apparatus 5 itself. A sleeve of the form taught in Fishman et al. or Lenze et al. would have been obvious in order to ensure that a partial vacuum is created during donning and/or that the Sandmark artificial limb remains attached to the residual limb after donning, with further motivation having been provided by the advantages discussed by Fishman et al. (column 1, lines 42-48; column 2, lines 3-7 and 15-20; column 4, lines 11-16) or by the advantages presented by Lenze et al. (column 1, lines 46-52; column 2, lines 9-12, 16-19, and 27-33). Regarding claims 47 and 53, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform; it does not constitute a limitation in any patentable sense (*In re Hutchison*, 69 USPQ 138). MPEP 2106, section II. C., explains that language which suggests or makes optional but "does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation"; "examples of language that may raise a question as to the limiting effect of the language in a claim" are "adapted to" and "adapted for" clauses. Regarding claim 57, a check valve releasably coupled to the channel through base 7 would have been obvious in order to close off the opening and maintain the vacuum after donning. Regarding claims 57 and 58, connecting the pump 5 to the socket 8 via a check valve so as to provide a donning mechanism only would have been an obvious variation in order to simplify the device and to prevent air leakage into the socket cavity immediately after donning.

Claims 50, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenze et al., US 5,376,131, which includes all the elements except, apparently, for the valve 2 being removably coupled to the distal end of the socket 1. Such a feature was well known in the

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art and would have been obvious, if not inherent, in order to facilitate assembly of the suction socket or replacement of the valve. Regarding claim 57, element 2 defining both a channel and a check valve would have been immediately obvious, if not inherent, from column 3, lines 31-34, and the check valve being releasably coupled to the channel would have been inherent from column 3, lines 34-37, and column 4, lines 62-64.

Claims 44, 47, 49, 50, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catranis, US 2,530,285, in view of Fishman et al., US 5,007,937, or Lenze et al., US 5,376,131, which discloses a valve assembly (Figure 2) including a base 37 and/or 21 and a duct 21 and/or 23. Catranis apparently lacks a sleeve to be worn over the residual limb. A sleeve of the form taught in Fishman et al. or Lenze et al. would have been obvious in order to ensure that the partial vacuum is maintained (column 1, lines 14-15) for various residual limb forms, with further motivation having been provided by the advantages set forth in Fishman et al. (column 1, lines 42-48; column 2, lines 3-7 and 15-20; column 4, lines 11-16) or Lenze et al. (column 1, lines 46-52; column 2, lines 9-12, 16-19, and 27-33).

Claims 79 and 80 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Toles, US 980,457. The base 18 includes two channels 19' connected to a central duct and a valve 15. The upright assembly comprises elements 20, 22, and 24. An attachment mechanism comprises fingers 21 for releasably attaching the upright assembly to an exterior distal end of the prosthetic limb socket 12 and 16 (page 2, lines 6-18). A valve 15 is coupled to the base 18 and controls the flow of air through the channels (page 1, lines 101-104; page 2, lines 62-65).

Claim 83 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Surerus, DE 27 29 800 A1, which includes a prosthetic limb socket 1, a base-plate (just under the pneumatic

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ring **22**), a channel opening onto the pneumatic ring **22**, a port (Figure 1), and a pump (English abstract, last sentence).

Claims 81-82 are allowed.

The Applicant's remarks have been reviewed. Regarding Surerus, the channel is defined by the tubular portion connected to the pneumatic ring **22** and extending through the base plate. The word "end" is defined as "[e]ither extremity of an object having length", and "extremity" means "[t]he outermost point *or portion*" (*Webster's II New Riverside University Dictionary*, 1984; emphasis added). Since the Applicant's "distal end" is certainly not limited to a single point and since the Applicant's base plate is not located at the most distal points of the socket (because otherwise there would be no need for through holes in the distal end of the socket: US 5,702,489; column 5, lines 33-44), the Surerus base plate is likewise deemed to be located in a distal end or portion of the socket. Regarding Toles, the examiner agrees with the Applicant's comments regarding the liner. The Applicant appears to have misunderstood how the examiner has interpreted the prosthetic limb socket in the Toles invention, so this element is explicitly addressed in the above grounds of rejection. Regarding Catranis, the examiner agrees that the valves work somewhat differently (the Catranis device providing upper and lower limits on the pressure), but such distinctions are not set forth in the rejected claims. Regarding Sandmark, the examiner is unable to locate an English translation of this document and there is no evidence in the file that such a translation was submitted. It is requested that the Applicant submit a copy of said translation if there is one in the Applicant's possession. As for the Declaration under 37 CFR 1.132, it is seen from the Fishman et al. and Lenze et al. teachings that sleeves and liners in

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conjunction with a suction suspension system were known and are compatible with the Catranis, the Sandmark, and numerous other prior art external limb prostheses.

The Applicant's amendments pertaining to the action of the valve and the liner-covered residual limb and other added limitations necessitated modifications to the grounds of rejection. Therefore:

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**